

## **REMARKS**

Reconsideration and withdrawal of the rejections set forth in the Office action dated February 1, 2006 are respectfully requested.

### **I. Amendments**

Claims 3, 7, 20-22, 24, 27-29, 31, and 32 are canceled.

Claims 1, 13, 14, and 18 are amended to recite "wherein the genome of the virus is inactivated, and wherein the virus belongs to the herpesviridae family." Basis for these amendments can be found on page 4, lines 6-9 and claims 3, 24, 27, and 31.

Claims 5 and 16 are amended to recite "inactivating the virus" as in claims 7 and 29.

Claim 8 is amended to depend from claim 6.

Claims 13, 14, 16, and 18 are amended to depend from claims of any one of claims 1-2, 5-6, 8-9, or 11-12.

No new matter has been added by way of these amendments.

### **II. Election/Restrictions**

Applicant hereby affirms the election of Herpesviridae as the species in claims 3, 24, 27, and 31, without traverse. It is Applicant's understanding that pending claims 1-2, 5-6, 8-9, 11-14, 16, 18, 23, 26, and 30 read on the elected species. Upon allowance of the generic claims, the Applicant request consideration of claims to additional species which are written in dependent form or which otherwise include all the limitations of the allowed generic claim(s) as provided by 37 C.F.R. §1.141.

### **III. Priority**

Applicant has updated the status of the parent applications in the cross-reference on page one of the instant application in accord with the Examiner's kind suggestion.

### **IV. Rejection under 35 U.S.C. §112, second paragraph**

Claims 8 and 9 were rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter

which the applicant regards as the invention. Specifically, the Examiner objected to the language "the detergent" for antecedent basis. Claim 8 is amended to properly depend from claim 6, which provides proper antecedent basis for the language. In light of these amendments, Applicant respectfully requests withdrawal of the rejections under 35 U.S.C. §112, second paragraph.

V. Rejection under 35 U.S.C. §102

Claims 1, 2, 5-7, 11-15, 18, 20, 23, 26, and 30 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by Hoon *et al.* (U.S. Patent No. 6,472,375).

Claims 1, 2, 5-7, 11-15, 18, 20, 23, 26, and 30 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by Hoon *et al.* (U.S. Patent No. 6,432,925).

Claims 1, 2, 5-8, 11-16, 18, 20, 21, 23, 26, 29, and 30 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Ramani *et al.* (*PNAS USA*, 95:11886-11890, 1998).

Claims 1-3, 5, 11-14, 16, 18, 23, 24, 26, 27, 30, and 31 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Roizman (U.S. Patent No. 5,846,707).

A. The Present Invention

The presently claimed invention relates to a gene transfer vector comprising an exogenous gene encapsulated in a native virus envelope (claim 1); a pharmaceutical composition comprising the gene transfer vector (claim 13); a kit for screening gene libraries comprising the gene transfer vector (claim 14); a method for preparing the gene transfer vector (claim 16); and a method for introducing a gene into an isolated animal tissue with the gene transfer vector (claim 18).

B. The Cited References

HOON ET AL., THE '375 PATENT The '375 patent was published on October 29, 2002 and names as co-inventors Dave S.B. Hoon and Yasufumi Kaneda. Mr. Kaneda is the sole inventor of the instant application. The present application was filed February 21, 2002 and claims priority to PCT application no. PCT/JP01/00782, filed February 2, 2001, which claims priority to Japanese application no. 25596, filed February 2, 2000.

Under M.P.E.P. § 715.01(a) and § 716.10, when subject matter, disclosed but not claimed in a patent or application publication filed jointly by S and another, is claimed in a later application filed by S, he or she may overcome the rejection by filing an unequivocal declaration that he/she conceived or invented the subject matter disclosed in the patent or application publication and relied upon in the rejection. Disclaimer by the other patentee or applicant of the application publication should not be required.

Enclosed herewith is a declaration by Mr. Yasufumi Kaneda, as filed in parent application no. 09/937,839, showing that he conceived or invented the subject matter disclosed in the '375 patent and relied upon in the present rejection. Specifically, and as stated in point 3 of the Declaration, the immunization protocol relied on in the present rejection was conceived of by Mr. Kaneda and thus represents the Applicant's own work. Accordingly, the '375 patent is not available as prior art under 35 U.S.C. §102(e).

HOON ET AL., THE '925 PATENT The '925 patent was published on August 13, 2002 and names as co-inventors Dave S.B. Hoon and Yasufumi Kaneda. Mr. Kaneda is the sole inventor of the instant application. The present application was filed February 21, 2002 and claims priority to PCT application no. PCT/JP01/00782, filed February 2, 2001, which claims priority to Japanese application no. 25596, filed February 2, 2000. Applicant will forward such a Declaration under 37 C.F.R. § 1.132 by Mr. Yasufumi Kaneda showing that he conceived or invented the subject matter disclosed in the '925 patent and relied on in the present rejection under separate cover. Accordingly, the '925 patent is not available as prior art under 35 U.S.C. §102(e).

RAMANI ET AL. disclose an engineered viral envelope using only the fusion glycoprotein for delivery of a reporter gene.

ROIZMAN describes insertion of a foreign gene into a viral genome under the control of promoter-regulatory regions of the genome to produce recombinant viruses.

### C. Analysis

#### 1. Rejection over Hoon et al. the '375 patent

As noted above, the '375 patent is not effective prior art.

2. Rejection over Hoon et al., the '925 patent

As noted above, the '925 patent is not effective prior art.

3. Rejection over Raimani et al.

Raimani *et al.* fail to teach a gene transfer vector comprising an exogenous gene encapsulated in a native virus envelope. Raimani *et al.* further fail to teach a method of making a gene transfer vector comprising an exogenous gene encapsulated in a native virus envelope or using the vector to introducing a gene into animal tissue. Raimani *et al.* teach an engineered viral envelope using only the fusion glycoprotein. Further, Raimani *et al.* teach the F-virosomes are prepared from a solubilized fraction containing Sendai virus envelope devoid of hemagglutinin-neuraminidase (HN) protein (see page 11866, right-hand column, lines 13-16).

4. Rejection over Roizman

Roizman fails to teach that the genome of the virus from which the vector is derived is inactivated as presently claimed. Instead, Roizman teaches insertion of a foreign gene into an intact viral genome by cotransfection to produce recombinant viruses (see Abstract and Col. 4, lines 25-26).

VI. Obviousness Double-Patenting Rejection

Claims 1, 2, 5-7, 11-14, 16, 18, 20, 23, 26, 29, and 30 were rejected under the judicially created doctrine of obviousness-type double patenting as being directed to an invention not patentably distinct from claims 1-7 of U.S. Patent No. 6,913,923.

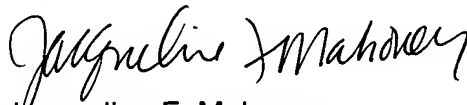
Claims 1, 2, 5-9, 11-14, 16, 18, 20-23, 26, 29, and 30 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being directed to an invention not patentably distinct from claims 20-49 of co-pending application no. 11/126,770.

Claims 1, 2, 5-7, 11-14, 16, 20, 23, and 26 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being directed to an invention not patentably distinct from claims 22-23 of co-pending application no. 10/485,752.

A Terminal Disclaimer prepared in accordance with 37 C.F.R. §1.321(b) and (c) is enclosed. The signed Terminal Disclaimer will obviate the above obviousness-type double patenting rejection.

If in the opinion of the Examiner a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 838-4410.

Respectfully submitted,



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